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FEB - 3 2009

510(k) Summary
COULTER® Body Fluid Control

1. **Submitted By:**

Lourdes Coba
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 SW 147 Avenue, M/C: 31-B06
Miami, Florida 33196-2500
Telephone: (305) 380-4079
FAX: (305) 380-4344

2. **Date Submitted:**

July 30, 2008

3. **Device Name(s):**

3.1 **Proprietary Names**

COULTER® Body Fluid Control

3.2 **Classification Name**

Hematology quality control mixture
(21 CFR § 864.8625)

4. **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
COULTER® Body Fluid Control	COULTER® 5C® Cell Control (Cleared as COULTER® PX Cell Control)	Beckman Coulter, Inc.	K912133 & K060464

5. **Description:**

Body Fluid Control is a reference product prepared from treated, stabilized human erythrocytes suspended in an isotonic medium. Body Fluid Control also contains a stabilized, platelet-sized component, and fixed erythrocytes to simulate leukocytes. Body Fluid Control confirms and monitors instrument accuracy and precision performance by providing measurements during counting.

6. **Intended Use:**

Body Fluid Control is a hematology quality control material used to monitor the performance and verify the measuring range of the body fluid cycle of the UniCel® DxH 800 COULTER Cellular Analysis System. Refer to the System HELP or Instructions for Use.

The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor performance, and verify the measurable range. This product can also be used to establish your own laboratory mean.

7. **Comparison to Predicate(s):**

COULTER Body Fluid Control is similar to the current COULTER 5C Cell Control except for the number of parameters reported and their respective concentrations. The product is used to monitor the RBC and TNC (white blood cells) measurements from the Body Fluid cycle on the UniCel® DxH 800 analyzer (pending 510(k) clearance K081930).

8. **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution. Stability studies of Body Fluid Control support the Beckman Coulter stability claims of 18 events within 16 days (open vial) and 120 days (closed vial).

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Beckman Coulter, Inc.
c/o Ms. Lourdes Coba
Staff Regulatory Affairs Specialist
11800 SW 147th Avenue
Miami, FL 33196

FEB - 3 2009

Re: k082162

Trade/Device Name: Coulter® Body Fluid Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: January 06, 2009
Received: January 07, 2009

Dear Ms. Coba:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Maria M. Chan".

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: COULTER® Body Fluid Control

Indications For Use:

Body Fluid Control is a hematology quality control material used to monitor the performance and verify the measuring range of the body fluid cycle of the UniCel® DxH 800 COULTER Cellular Analysis System. Refer to the System HELP or Instructions for Use.

The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor performance, and verify the measurable range. This product can also be used to establish your own laboratory mean.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Josephine B. [Signature]
Office of In Vitro Diagnostic Devices
Evaluation

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